

There is a letter that has been gone over in some depth and length from the Food and Drug Commissioner saying that it is going to be very difficult for them to certify the safety of these drugs. Yet what the Lautenberg amendment does is it says: OK, if you can certify safety, and this is going to reduce the price, then they can be admitted.

That seems to make sense. That is why 4 times over the last 10 years this body has passed the Lautenberg amendment, or an equivalent, and I think that is appropriate.

I would also note there is a huge industry in the United States—the pharmaceutical industry—that is quite concerned about the safety and efficacy of what this bill would do in not allowing the safety of the drugs if you don't pass a Lautenberg amendment. They are very concerned about that. And toward that regard, I will read pieces of a letter sent to me by Kansas Bio. It is the Kansas Biosciences Organization. They sent this letter to me saying:

On behalf of the members of Kansas Bio, please accept this letter in opposition to Senator Dorgan's drug importation amendment to the health care reform legislation which may be voted on by the Senate. We believe that the promotion of drug importation is an extremely risky endeavor which threatens the livelihood of one of Kansas' fastest growing bioscience industry sectors—the service providers to our Nation's and our world's drug development and delivery companies.

KansasBio is an industry organization representing over 150 bioscience companies, academic institutions, State affiliates, and related economic development organizations in the State of Kansas, throughout the Kansas City region. . . . Senator DORGAN's amendment opens up the risk of allowing foreign drugs that do not have FDA approval into the United States and thereby posing significant health and safety risks to the patients.

It is signed by the president and CEO, Angela Kreps, of KansasBio.

I am ranking member on the Senate Appropriations Subcommittee on Agriculture, Rural Development, and the Food and Drug Administration, so I am keenly interested in the committee structure in this issue.

In addition, the University of Kansas in my State, in addition to having the top-ranked basketball team in the country, has the top-ranked pharmaceutical school in the country. They are a part of KansasBio and concerned about the Dorgan amendment in place. That is why they support things like the Lautenberg amendment which assure two things: that you have safety and that any value in this proposal is passed along to the consumer.

The FDA has been tasked with the responsibility of safeguarding this country's prescription drug supply and has executed that responsibility, I believe, quite well. It would be unwise for this body, then, to not value their opinions in regard to this matter. The Lautenberg amendment counts on the FDA expertise and proven track record and permits legal importation of prescription drugs into the United States

only if Secretary of Health and Human Services, Secretary Sebelius in this administration, as head of the FDA, can certify to Congress that prescription drug importation will do two things: No. 1, pose no additional risk to the public health and safety; and, No. 2, result in a significant reduction in the cost of covered products to the American consumer. The safety and cost savings certification amendment would restore this language.

The Lautenberg amendment does that. This Congress must require a safety and cost savings certification from the Secretary of HHS before opening the floodgates of drug importation. Requiring this certification is the responsible way to ensure that American citizens will be protected from potentially life-threatening counterfeit, contaminated, or diluted prescription drugs.

As I mentioned, the Senate has voted on this previously four times, each time overwhelmingly adopting something like the Lautenberg amendment. As many of my colleagues may remember, the safety and cost savings certification was first signed into law when the Senate passed the Medicine Equity and Drug Safety Act of 2000. During that debate, concerns were raised by many in this body that drug importation would expose Americans to counterfeit and polluted prescription drugs. To alleviate these well-documented fears, the Senate passed this second-degree amendment then unanimously.

To date, as noted earlier, no HHS Secretary has been able to certify that drug importation will not pose a significant health and safety threat. For those reasons, I support the Lautenberg amendment.

I yield the floor.

The PRESIDING OFFICER. The time of the Senator has expired.

The Senator from New Jersey is recognized.

Mr. LAUTENBERG. Mr. President, I think we have some time available. I wish to continue with some remarks. I thank the Senator from Kansas for his remarks and his concern also about the efficacy and the safety of drugs that might reach our citizens.

I listened carefully to the remarks of my colleague from North Dakota. He said the principal focus of our amendment is to protect the profits of the drug companies. No, I want to protect the health and well-being of American citizens. I look at an industry that has prolonged life expectancy, has made life more productive and pleasant for many whose disabilities may have them imprisoned in their homes.

We look at what has happened over the years, where treatment for conditions such as malaria, polio, smallpox were discovered, and antibiotics and chemotherapy have continued to be developed, primarily by American drug companies. Those are the companies that have the reputation for bringing the best products to market, the most carefully scrutinized, and most effective.

What I want is for those companies to continue to be developing drugs that will extend wellness and will continue to improve longevity. I want these products to be available more reasonably, more cheaply—more affordably.

I had an experience in my life—people have heard me talk about this at times—whereby my father got cancer, was disabled with cancer when he was 42 years old. Our family was virtually bankrupt as a result of the cost for drugs and hospital services and physicians, so I know how costly they are. My father had cancer then, and I have seen what has happened now, with the opportunities for some optimism in situations where cancer develops. We are looking to make these drugs more available, more affordable.

The thing that strikes me, as we review where we are in the development of a new health plan or a reform of the existing health programs, and I hear the criticism coming from people who have indicated they do not support more available health products, I think about what happens when votes come about that move the health care bill along. There is absolute obstinacy that prevails with many of our friends on the Republican side.

I look at what good, proper products can do and the hope we have for childhood diseases that are so painful to see. We look for improvements in those—whether it is autism or diabetes or other conditions. We want desperately for companies in this country of ours to continue to develop drugs to treat them—or companies anywhere. But when they come to this country we have to know they are safe because there is nothing that can excuse the sacrifice of safety, for whatever discounts you might get on the product, products that, as has been noted, can kill you if they are the wrong formula or contaminated product.

Our differences between the Dorgan and Lautenberg amendments boil down to one word: safety. Knowing that when you open the bottle, that when you take the liquid, you are not doing something or your children or your loved ones are not doing something that harms their health. We owe them that feeling of security and comfort as they try to cure themselves from sickness or disease. That is what we are looking at here. I hope my colleagues will stand up and say no, don't let these products come in without the tightest scrutiny that can be developed; without the most secure process of production and shipment that can be exercised.

I yield the remainder of my time.

The PRESIDING OFFICER. Who yields time?

The Senator from Montana.

Mr. BAUCUS. Mr. President, I ask how many minutes I have remaining.

The PRESIDING OFFICER. The Senator has 15 minutes remaining.

Mr. BAUCUS. I yield 5 minutes to my good friend from Iowa who I think is